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Date: February 12, 2009 Signature: _____ (Quyen Nguyen)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/612,491
Confirmation No.:	3557
Filing Date:	July 1, 2003
Inventor(s):	Vahid SAADAT et al.
Title:	METHODS FOR REDUCTION OF A GASTRIC LUMEN
Examiner:	Yabut, Diane D.
Group Art Unit:	3734

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Appeal Brief for the above-identified application in which pending claims 1-7, 9, 16, 26-27, and 32-40 were rejected in a Final Office Action mailed April 15, 2008 ("the Office Action").

A Notice of Appeal was filed in this case on September 12, 2008. The fees required for filing this Appeal Brief are transmitted herewith. The Commissioner is authorized to charge **Deposit Account No. 50-3973** for any other fees that may be due with this Appeal.

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I. REAL PARTY IN INTEREST

The Application is assigned to USGI Medical Inc., a Delaware Corporation having its principal place of business at 1140 Calle Cordillera, San Clemente, California 92673.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF THE CLAIMS

Claims 1-7, 9, 16, 26-27, and 32-40 were finally rejected and are the subject of this Appeal. Claims 8, 10-15, 17-25, and 28-31 were cancelled.

IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to final rejection of the claims.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of independent claims, as well as those dependent claims to which separate arguments are being presented, as required by 37 C.F.R. § 41.37(c)(1)(v), and a non-limiting list of locations where support may be found [bracketed citations] is provided as follows:

The claims on appeal describe methods for delivering and deploying a tissue anchor into tissue of the gastrointestinal lumen of a patient for the purpose of, for example, reducing the cross-sectional area or volume of the gastrointestinal lumen in order to promote weight loss. An exemplary embodiment of the claimed subject matter is set forth in at least Figures 10A-D and 12, which are reproduced below, and is described in the specification at least at Paragraphs 0062-0066.

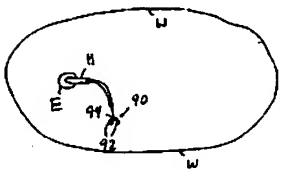


FIG. 10A

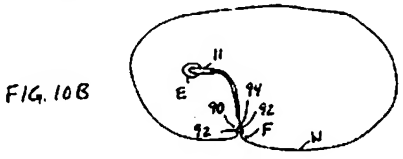


FIG. 10B

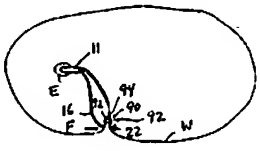


FIG. 10C

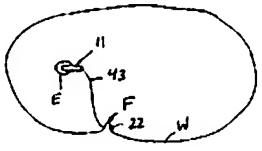


FIG. 10D

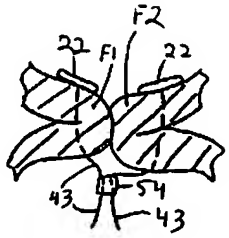


FIG. 12

Figures 10A-D show a delivery catheter 11 having a translatable needle 16 and a deployable stabilization device (jaw assembly 90). The jaw assembly 90 is used to grab and pull tissue from the tissue wall W to create a tissue fold F, as shown in Fig. 10B. The creation of the tissue fold F facilitates penetration of the tissue wall W by the needle 16

and subsequent delivery of an anchor assembly 22. The jaw assembly 90 and needle 16 are then retracted into the delivery catheter 11 as the tissue fold F is maintained by applying tension to the suture 43. The process is repeated to create additional tissue folds, which are approximated by applying tension to the sutures and then tying the sutures together or, alternatively using a fastener 54 to maintain the folds in the approximated position, as shown in Fig. 12.

Turning to the specific claims, **claim 1** describes a method for delivering an anchor for use in a gastric reduction system for reducing the cross-sectional area of a gastrointestinal lumen. [Paragraph 0035, lines 3-10]. The method includes providing a delivery catheter having a stabilization device disposed at its distal end. [Paragraph 0036, lines 1-8; Paragraph 0038, lines 1-6; Paragraph 0062, lines 3-5; Figs. 1-3, 10A-D]. A needle is translatably disposed in the catheter, and one or more anchors are disposed within the needle. [Paragraph 0036, lines 4-6; Paragraph 0037, lines 1-7; Figs. 1-2].

The delivery catheter is advanced into the gastrointestinal lumen, where the stabilization device is engaged to a tissue wall of the gastrointestinal lumen. [Paragraph 0053, lines 3-6; Paragraph 0055, lines 1-4; Paragraph 0063, lines 2-8; Figs. 8A-H, 10A-B]. The needle is advanced through the tissue wall, and an anchor having an attached suture is ejected from the distal tip of the needle. [Paragraph 0055, lines 4-9; Paragraph 0064, lines 1-5; Figs. 8B-C, 10C]. The needle is then withdrawn from the tissue wall, leaving the suture extended through the tissue wall. [Paragraph 0055, lines 9-14; Paragraph 0064, lines 5-9; Figs. 8C, 10D]. A fastener is translated over the suture to create a tension force on the suture to maintain the tissue fold. [Paragraph 0056, line 1 through paragraph 0058, line 3; Paragraph 0064, lines 11-15; Paragraphs 0065-0066; Figs. 6, 8D-G, 10D, and 12].

Claim 6 describes a method suitable for delivering an anchor for use in a gastric reduction system for reducing the cross-sectional area of a gastrointestinal lumen. [Paragraph 0035, lines 3-10]. The method includes providing a delivery catheter including a piercing element within the catheter. [Paragraph 0036, lines 1-8; Paragraph 0062, lines 3-5; Figs. 1-3, 10A-D]. One or more anchors are disposed within the needle,

and a suture is coupled to the one or more anchors. [Paragraph 0037, lines 1-7; Figs. 1-2].

The delivery catheter is advanced into the gastrointestinal tract. [Paragraph 0053, lines 3-6; Paragraph 0063, lines 2-8; Figs. 8A-H, 10A-B]. The piercing element is advanced through a first tissue wall, [Paragraph 0055, lines 4-7; Paragraph 0064, lines 1-3; Fig. 8B, 10C], and then a second tissue wall, [Paragraph 0055, lines 9-11; Paragraph 0064, lines 9-11; Fig. 8C]. A first anchor having an attached suture is ejected from the piercing element on a first side of the first tissue wall, [Paragraph 0055, lines 4-9; Paragraph 0064, lines 1-5; Fig. 8B, 10C], then a second anchor having an attached suture is ejected from the piercing element on a second side of the second tissue wall, [Paragraph 0055, lines 9-11; Paragraph 0064, lines 9-11; Fig. 8C]. A fastener is translated over the suture to create a tension force on the suture such that the first and second anchors and the suture hold the first tissue wall adjacent to the second tissue wall. [Paragraph 0056, line 1 through paragraph 0058, line 3; Paragraph 0064, lines 11-15; Paragraphs 0065-0066; Figs. 6, 8D-G, 10D, and 12].

Claim 26 describes a method for creating a gastrointestinal tissue fold. [Paragraph 0062, lines 1-3; Figs. 10A-D]. The method includes providing a delivery catheter including a translatable needle within the catheter. [Paragraph 0036, lines 1-8; Paragraph 0062, lines 3-5; Figs. 1-3, 10A-D]. One or more anchors are disposed within the needle, and a suture is coupled to the one or more anchors. [Paragraph 0037, lines 1-7; Figs. 1-2].

The tissue wall of the gastrointestinal lumen is engaged and pulled to create a tissue fold. [Paragraph 0063, lines 6-8; Fig. 10B]. The needle is advanced through the tissue fold, and an anchor having an attached suture is ejected from the needle. [Paragraph 0064, lines 1-5; Fig. 10C]. The needle is then withdrawn from the tissue fold, leaving the suture extended through the tissue fold. [Paragraph 0064, lines 5-9; Fig. 10D]. A fastener is translated over the suture to create a tension force on the suture to maintain the tissue fold. [Paragraph 0056, line 1 through paragraph 0058, line 3; Paragraph 0064, lines 11-15; Paragraphs 0065-0066; Figs. 6, 8D-G, 10D, and 12].

Claim 32 describes a method suitable for delivering an anchor for use in a gastric reduction system for reducing the cross-sectional area of a gastrointestinal lumen. [Paragraph 0035, lines 3-10]. The method includes providing a catheter including a piercing element within the catheter. [Paragraph 0036, lines 1-8; Paragraph 0062, lines 3-5; Figs. 1-3, 10A-D]. The piercing element is adapted to deploy first and second anchors, and a suture is coupled to the first and second anchors. [Paragraph 0037, lines 1-7; Figs. 1-2].

The catheter is advanced into the gastrointestinal tract of the patient. [Paragraph 0053, lines 3-6; Paragraph 0063, lines 2-8; Figs. 8A-H, 10A-B]. The tissue wall of the gastrointestinal tract is held to create a tissue fold. [Paragraph 0063, lines 6-8; Fig. 10B]. The piercing element is extended from the catheter and through the tissue fold, [Paragraph 0064, lines 1-3; Fig. 10C], and then through a second tissue fold, [Paragraph 0064, lines 9-11; Fig. 10D]. A first anchor having an attached suture is ejected from the piercing element on a first side of the first tissue fold, [Paragraph 0064, lines 1-5; Fig. 10C], then a second anchor having an attached suture is ejected from the piercing element on a second side of the second tissue fold, [Paragraph 0064, lines 9-11; Fig. 10D]. A fastener is translated over the suture to create a tension force on the suture such that the first and second anchors and the suture hold the first tissue fold adjacent to the second tissue fold. [Paragraph 0056, line 1 through paragraph 0058, line 3; Paragraph 0064, lines 11-15; Paragraphs 0065-0066; Figs. 6, 8D-G, 10D, and 12].

Claim 35 describes a method of creating a tissue fold. [Paragraph 0062, lines 1-3; Figs. 10A-D]. The method includes providing a delivery catheter including a piercing element within the catheter. [Paragraph 0036, lines 1-8; Paragraph 0062, lines 3-5; Figs. 1-3, 10A-D]. One or more anchors are disposed within the piercing element, and a suture is coupled to the one or more anchors. [Paragraph 0037, lines 1-7; Figs. 1-2].

The catheter is advanced into a surgical site of the patient, such as the gastrointestinal lumen. [Paragraph 0053, lines 3-6; Paragraph 0063, lines 2-8; Figs. 8A-H, 10A-B]. The tissue wall of the gastrointestinal lumen is engaged and pulled to form a tissue fold. [Paragraph 0063, lines 6-8; Fig. 10B]. The piercing element is pushed out of

the catheter and through the tissue fold, and a first anchor having an attached suture is ejected from the piercing element. [Paragraph 0064, lines 1-5; Fig. 10C]. The piercing element is then withdrawn from the tissue fold. [Paragraph 0064, lines 5-9; Fig. 10D]. A second anchor having an attached suture is then ejected from the piercing element. [Paragraph 0055, lines 9-11; Paragraph 0064, lines 9-11; Fig. 8C]. A fastener is translated over the suture to create a tension force on the suture to maintain the tissue fold. [Paragraph 0056, line 1 through paragraph 0058, line 3; Paragraph 0064, lines 11-15; Paragraphs 0065-0066; Figs. 6, 8D-G, 10D, and 12].

Claim 38 describes a method suitable for delivering an anchor for use in a gastric reduction system for reducing the cross-sectional area of a gastrointestinal lumen. [Paragraph 0035, lines 3-10]. The method includes providing a system having a delivery catheter including a translatable needle within the catheter. [Paragraph 0036, lines 1-8; Paragraph 0062, lines 3-5; Figs. 1-3, 10A-D]. One or more anchors are disposed within the needle, and a suture is coupled to the one or more anchors. [Paragraph 0037, lines 1-7; Figs. 1-2].

The tissue wall of the gastrointestinal tract of a patient is engaged and pulled to create a tissue fold. [Paragraph 0063, lines 6-8; Fig. 10B]. The needle is extended through the tissue fold, and a first anchor having an attached suture is ejected from the needle. [Paragraph 0064, lines 1-5; Fig. 10C]. The needle is then withdrawn from the tissue fold and the tissue fold is released. [Paragraph 0064, lines 5-7; Fig. 10D]. A second anchor having an attached suture is then ejected from the piercing element. [Paragraph 0055, lines 9-11; Paragraph 0064, lines 9-11; Fig. 8C]. A fastener is translated over the suture to create a tension force on the suture to maintain the tissue fold. [Paragraph 0056, line 1 through paragraph 0058, line 3; Paragraph 0064, lines 11-15; Paragraphs 0065-0066; Figs. 6, 8D-G, 10D, and 12].

Claim 39 describes a method suitable for delivering an anchor for use in a gastric reduction system for reducing the cross-sectional area of a gastrointestinal lumen. [Paragraph 0035, lines 3-10]. The method includes using a catheter including an extendable piercing element. [Paragraph 0036, lines 1-8; Paragraph 0062, lines 3-5; Figs. 1-3, 10A-D]. One or more anchors are disposed within the piercing element, and a

connection element is coupled to the one or more anchors. [Paragraph 0037, lines 1-7; Figs. 1-2].

The catheter is moved into the patient. [Paragraph 0053, lines 3-6; Paragraph 0063, lines 2-8; Figs. 8A-H, 10A-B]. A tissue wall is pulled and held to form a tissue fold. [Paragraph 0063, lines 6-8; Fig. 10B]. The piercing element is pushed out of the catheter and through the tissue fold, and a first anchor having an attached suture is ejected from the piercing element. [Paragraph 0064, lines 1-5; Fig. 10C]. The piercing element is then withdrawn from the tissue fold. [Paragraph 0064, lines 5-9; Fig. 10D]. A second anchor having an attached suture is then ejected from the piercing element. [Paragraph 0055, lines 9-11; Paragraph 0064, lines 9-11; Fig. 8C]. The tissue fold is held via the connection element extending between the two anchors. [Paragraph 0056, line 1 through paragraph 0058, line 3; Paragraph 0064, lines 11-15; Paragraphs 0065-0066; Figs. 6, 8D-G, 10D, and 12].

Finally, **claim 40** describes a method suitable for delivering an anchor for use in a gastric reduction system for reducing the cross-sectional area of a gastrointestinal lumen. [Paragraph 0035, lines 3-10]. The method includes using a catheter including a tissue grasper and an extendable piercing element. [Paragraph 0036, lines 1-8; Paragraph 0062, lines 3-5; Paragraph 0063, lines 1-2; Figs. 1-3, 10A-D]. One or more anchors are disposed within the piercing element, and a connection element is coupled to the one or more anchors. [Paragraph 0037, lines 1-7; Figs. 1-2].

The catheter is moved into the patient. [Paragraph 0053, lines 3-6; Paragraph 0063, lines 2-8; Figs. 8A-H, 10A-B]. The tissue grasper is used to form and hold a tissue fold. [Paragraph 0063, lines 6-8; Fig. 10B]. The piercing element is pushed out of the catheter and through the tissue fold, and a first anchor having an attached suture is ejected from the piercing element. [Paragraph 0064, lines 1-5; Fig. 10C]. The piercing element is then withdrawn from the tissue fold. [Paragraph 0064, lines 5-9; Fig. 10D]. A second anchor having an attached suture is then ejected from the piercing element. [Paragraph 0055, lines 9-11; Paragraph 0064, lines 9-11; Fig. 8C]. The tissue fold is held via the connection element extending between the two anchors. [Paragraph 0056, line 1 through

paragraph 0058, line 3; Paragraph 0064, lines 11-15; Paragraphs 0065-0066; Figs. 6, 8D-G, 10D, and 12].

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the Examiner erred in rejecting claims 1, 3-7, 9, 26-27, and 32-38 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,056,760 to Koike et al. (hereinafter "Koike") in view of U.S. Patent No. 6,746,460 to Gannoe et al. ("Gannoe"), U.S. Patent Application Publication No. 2004-0194790 to Laufer et al. ("Laufer"), and U.S. Patent No. 7,186,262 to Saadat ("Saadat").

2. Whether the Examiner erred in rejecting claims 2 and 16 under 35 U.S.C. § 103(a) as being unpatentable over Koike in view of Gannoe, Laufer, Saadat, and U.S. Patent No. 6,352,503 to Matsui et al. ("Matsui").

3. Whether the Examiner erred in rejecting claims 39 and 40 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,835,199 to McGuckin, Jr. et al. ("McGuckin") in view of U.S. Patent No. 6,736,828 to Adams et al. ("Adams").

VII. ARGUMENT

A. The Office erred in rejecting claims 1, 3-7, 9, 26-27, and 32-38 under 35 U.S.C. § 103(a) as being unpatentable over the Koike patent in view of the Gannoe patent, the Laufer publication, and the Saadat patent.

(1) Claims 1, 6, and 38 and claims dependent therefrom

Claims 1, 6, and 38 are presented below:

1. A method for delivering an anchor for use in a gastric reduction system for reducing the cross-sectional area of a gastrointestinal lumen, comprising:

providing a delivery catheter having a needle translatably disposed therein, a distal end, a stabilization device disposed at the distal end and one or more anchors disposed within the needle;

advancing the delivery catheter into the gastrointestinal lumen;

engaging the stabilization device to a tissue wall of the gastrointestinal lumen;

advancing the needle through the tissue wall;

ejecting an anchor from a distal tip of the needle, the anchor having a suture attached thereto;

withdrawing the needle from the tissue wall whereby the suture is extended through the tissue wall; and

translating a fastener over the suture whereby a tension force is created on the suture and said tissue fold is maintained.

6. A method comprising:

providing a delivery catheter including a piercing element within the catheter, one or more anchors within the catheter and a suture coupled to the anchors;

advancing the delivery catheter into the gastrointestinal tract of a patient;

advancing the piercing element through a first tissue wall, and then through a second tissue wall;

ejecting a first anchor from the piercing element on a first side of the first tissue wall, and ejecting a second anchor from the piercing element on a second side of the second tissue wall; and

advancing a fastener over the suture whereby a tension is applied to the suture, the fastener comprising a collar having a central channel through which the suture extends;

such that the first and second anchors and the suture hold the first tissue wall adjacent to the second tissue wall.

38. A method comprising:

providing a system having a delivery catheter having a translatable needle and anchors disposed within the needle, and a suture coupled to the anchors;

engaging and pulling a tissue wall of the gastrointestinal tract of a patient to create a tissue fold;

extending the needle through the tissue fold;

placing an anchor on one side of the tissue fold;

releasing the tissue fold;

placing an anchor on the opposite side of the tissue fold, with the anchors connected to each other via the suture; and

advancing a fastener over said suture to apply a tension force on said suture;

with the anchors and suture maintaining the tissue fold after the tissue fold is released.

The Office rejected claims 1, 6-7, and 38 under 35 U.S.C. § 103(a), alleging the claims to be unpatentable over Koike in view of Gannoe, Laufer, and Saadat. As demonstrated below, the rejections set forth in the Office Action are based upon mischaracterizations of the teachings of the Gannoe and Laufer references. Once these mischaracterizations are corrected, it becomes clear that:

- there is no legitimate reason why a person of ordinary skill in the art would have been motivated to combine these references and modify their teachings in the manner suggested in the Office Action; and
- even if the references were combined, they fail to teach all of the limitations of Appellants' claims.

As a result, the claims at issue are demonstrably patentable.

Turning to the Office Action, the primary reference – Koike – describes an intracardiac suturing device. The device is designed for inserting into a peripheral blood vessel and manipulating into the heart by cardiocatheterization under cross-sectional echocardiography to sew an atrial septal defect (ASD) by direct suturing. (See Koike, col. 1, ll. 4-12). The Office Action lists several features of the Koike suturing device that are comparable to those recited in Appellants' claims – e.g., a sheath 1 ("delivery catheter"), a piercing catheter 2 ("needle" or "piercing element"), and an engaging member 4 attached to suture threads T1 or T2 ("anchors" attached to "sutures"). (Office Action, pp. 2-3). The Office Action also identifies several differences between the Koike suturing method and the recited anchor delivery and deployment methods, namely:

- the lack of a stabilization device disposed at the distal end of the delivery catheter;
- the missing step of "engaging the stabilization device to a tissue wall of the gastrointestinal lumen before advancing the catheter through the tissue wall;"
- the missing step of "advancing the delivery catheter and needle into the gastrointestinal lumen, or tract of a patient;" and
- the missing step of "translating a fastener over the suture whereby a tension force is created on the suture and said tissue fold is maintained."

(Office Action, pg. 3). The Office Action relies upon three additional references – Gannoe, Laufer, and Saadat – to supply the subject matter missing from the Koike patent.

The secondary reference – Gannoe – describes devices and methods used to attach space-occupying devices (e.g., balloons) that are placed in a patient's stomach to fill portions of the stomach to provide the patient with the feeling of fullness, thereby reducing food intake. (Gannoe, col. 1, ll. 5-10). The tertiary reference, Laufer, describes a device used to reconfigure tissue in the vicinity of the gastroesophageal junction for the treatment of gastroesophageal reflux disease (GERD). (Laufer, paragraph 0002). The Laufer device includes an elongated shaft with an end effector having a pair of jaws, one of which has a pair of tissue penetrating tips. (Laufer, paragraphs 0094-0097, Figures 9A-F). After advancing the device down the esophagus and into the stomach, the tissue penetrating tips (818a, 818b) mounted on the jaws (720, 722) are used to penetrate the

stomach tissue. Finally, the Saadat patent teaches using a fastener 532 that is translated over a suture 506 to create tension in the suture and thereby to retain tissue. (Saadat, col. 24, ll. 42-58; Figure 49A).

An invention composed of several elements "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1741 (2007). Absent a legitimate reason why a person skilled in the art would have been motivated to make the proposed combination, no prima facie case of obviousness can be established. Such is the case here. More specifically, the devices and methods described in these four references are intended to address such completely different problems in such completely different ways that there can be no legitimate basis for combining them in the manner suggested in the Office Action. Several of the most significant differences – and the reasons why these differences negate any contention that it would have been obvious to combine the references – are discussed below.

First, it is important to recognize that the Koike device is designed for a purpose (intracardiac suturing) that is very different from stomach implant attachment (Gannoe) and/or stomach tissue reconfiguration (Laufer), and that the method of using the Koike device to achieve that purpose is also very different from the methods described in the Gannoe and Laufer references. For example, the Koike sheath 1 (containing the piercing catheter 2) is introduced into a patient's body through the femoral vein and is then maneuvered into the right atrium of the patient's heart. (Koike, col. 5, ll. 36-40; Fig. 5). As a result, the Koike catheter assembly must necessarily have a much smaller profile than what is required of a device designed for use in the gastrointestinal lumen,[1] and it would be impractical (or infeasible) for the Koike catheter assembly to accommodate additional functional elements, such as the Gannoe fasteners or the Laufer "stabilization device." It would not have been obvious to increase the size of the Koike sheath to accommodate these additional features, because doing so would prevent the Koike device

[1] Elsewhere in the patent, Koike states that a comparable procedure is carried out using an elongated sheath with a thickness of 11 French – i.e., a diameter of less than 3.7 mm. (Koike, col. 1, ll. 63-65). The Laufer device, on the other hand has a diameter in the range of 12-16 mm, (Laufer, paragraph 0088), i.e., about 3 to more than 4 times as large.

from being introduced through the vasculature, and would therefore render the Koike device unsuitable for its intended purpose. See MPEP § 2143.01(V.) ("The proposed modification cannot render the prior art unsatisfactory for its intended purpose."); In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Second, once the Koike catheter assembly is located in the patient's right atrium, the piercing needle 25 of the piercing catheter 2 is used to puncture the interatrial septum. The distal end of the catheter assembly is then advanced into the left atrium where an engaging member 4 is deployed. (Koike, col. 5, ll. 40-52; Figs. 6-7). Whereas Koike teaches that it is necessary to puncture through tissue separating two heart chambers, a comparable procedure in the gastrointestinal lumen (e.g., puncturing through the stomach wall into the abdominal cavity) is typically avoided due to the presence of other organs that are not under visualization. For example, the Gannoe patent states that the "fasteners are configured such that portions of the fasteners may extend at least partially through one or several folds of the patient's stomach wall, thereby maintaining the device within the patient's stomach, but do not extend external to the patient's body." (Gannoe, col. 2, ll. 14-22). Similarly, the Laufer reference teaches piercing through a portion of tissue that is pulled between the jaws, rather than puncturing through the stomach wall into the abdominal cavity. (Laufer, paragraphs 0094-0096, Figures 9A-F). These are different methods that are adapted to the differences in anatomy involved in cardiac procedures (Koike) and gastrointestinal procedures (Gannoe and Laufer). It is improper to simply choose features described in these references and combine them in a way that ignores any and all teachings to the contrary.

As yet another example, The Koike method is used to sew an atrial septal defect by direct suturing. (Koike, col. 1, ll. 4-12). The method entails joining two sections of interatrial septal tissue that are separated by a small defect or void – i.e., a piercing needle is pierced through each of the tissue sections, engaging members are pushed out of the piercing needle, and sutures extending from the engaging members are joined together. (Koike, col. 5, line 32 to col. 6, line 13; Figs. 5-10). The Gannoe method, on the other hand, is used to fasten a space-occupying device onto the wall of a stomach. (Gannoe, col. 1, ll. 52-57). This method is performed by attaching a fastener to a tissue fold

formed on the stomach wall – without piercing through the stomach wall to the exterior of the stomach – and then tethering the space-occupying device to the tissue fastener. (Gannoe, col. 2, ll. 14-22).

As best understood, the Office Action proposes to incorporate the Koike intracardiac suturing method (including use of the Koike delivery catheter, piercing needle, engaging member, and suture) into the Gannoe gastrointestinal space-occupying device fastening method. The proposed modification of the Koike method into the Gannoe method would require a substantial change in the basic operation of the Koike device, which itself negates any proposed prima facie case of obviousness. See MPEP § 2143.01(VI) ("The proposed modification cannot change the principle of operation of a reference."); In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). For example, instead of joining two sections of tissue, the modified Koike method would be used to join a tissue fold to a space-occupying device; which would require a substantial (yet unspecified) redesign of the Koike device and method in order to perform the tethering operation. As another example, the Koike delivery catheter and piercing needle are designed only to expel an engaging member from the distal end of the piercing needle, i.e., the device is not adapted to deploy any of the fasteners described in the Gannoe patent. Moreover, the Koike method teaches that the piercing needle is extended through a portion of tissue (rather than through a tissue fold) to the exterior tissue surface. Again, many substantial (yet unspecified) modifications would be needed to allow the Koike device to perform the proposed function. As yet another example, the Koike method entails advancing the piercing needle to pierce straight through a region of tissue lying directly in the path of the delivery catheter, whereas the Gannoe method requires deployment of a fastener through or onto the surface of a tissue fold that is formed on the interior stomach wall. Yet again, in order to perform this modified method, the principle of operation of the Koike device and method would need to be changed significantly. For these reasons, the Koike and Gannoe patents are inadequate to form the basis for a prima facie case of obviousness.

In presenting these arguments, Appellants are mindful that the test for obviousness is not whether the features of a secondary or ternary reference may be bodily

incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Appellants' arguments are directed exactly to this principle, and are intended to show that the combined teachings of the Koike, Gannoe, and Laufer references would not have led one of ordinary skill in the art to Appellants' claimed invention, for all of the reasons set forth above.

The lack of any basis for combining the Koike, Gannoe, and Laufer references is further demonstrated by the fact that the Office Action fails to set forth any legitimate rationale for making the combination. The Office Action states the following about Gannoe:

> Gannoe et al. teaches delivering the delivery catheter and needle, or tissue piercing element into the gastrointestinal lumen, or tract of a patient in order to reduce the amount of food desired by patients who may be obese (col. 1, lines 12-30 and 52-67).

This is a mischaracterization of the cited portions of the Gannoe patent. To be clear, the Gannoe patent does not describe a needle or tissue piercing element used to deliver an anchor – instead, the tissue piercing members are the anchors themselves. (See, e.g., Gannoe, col. 4, ll. 46-62; col. 5, line 49 to col. 6, line 18; Figs. 4A-C and 7A-B). In addition, the Gannoe "delivery catheter" and anchors are used to advance and anchor a space-occupying member to the stomach wall, i.e., they do not "reduce the amount of food desired by a patient who may be obese."

These mischaracterizations of what Gannoe teaches are fatal to the Office Action, because they constitute the only basis stated in the Office Action for combining the teachings of the Koike and Gannoe patents:

> It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a tissue piercing element into the gastrointestinal lumen, as taught by Gannoe et al., to Koike et al. in order to aid obese patients in managing the amount of food desired and eaten.

(Office Action, pg. 3). This contention not only fails to establish a prima facie case of obviousness, it does not even make sense. The only "tissue piercing elements" taught by Gannoe are the balloon anchors, which are not comparable to any of the components of

the Koike intracardiac suturing system. Moreover, the Koike patent has nothing to do with treating obesity, or with any procedures performed within the gastrointestinal lumen. It would make no sense, therefore, "to provide a tissue piercing element into the gastrointestinal lumen ... to Koike et al. in order to aid obese patients in managing the amount of food desired and eaten." Finally, even if the proposed combination was made, the result – Gannoe's rigid anchor attached to the stomach wall in combination with Koike's suturing device and method – would still fail to correct the deficiencies of the Koike patent that were explicitly set forth in the Office Action.[2]

As for the Laufer publication, the Office Action states, at page 3, that Laufer teaches:

> a stabilization device 740 disposed at the distal end, engaging the stabilization device to a tissue wall of the gastrointestinal lumen before advancing the catheter through the tissue wall (Figure 4A and page 3, paragraphs 79 and 83).

This is another mischaracterization. The Laufer publication does not teach the step of "advancing the catheter through the tissue wall." Instead, the Laufer method includes advancing into the stomach an instrument having an elongated shaft with an end effector having a pair of jaws, one of which has a pair of tissue penetrating tips. (Laufer, paragraphs 0094-0097, Figures 9A-F). It is the tissue penetrating tips (818a, 818b) mounted on the jaws (720, 722) of the Laufer device that are used to penetrate tissue; nowhere does Laufer teach advancing a catheter through a tissue wall.

Once again, this mischaracterization of the Laufer device and method is significant, because it is the only basis asserted in the Office Action for why it would have been obvious to combine the Laufer stabilization device with the combined teachings of the Koike and Gannoe patents:

> It would have been obvious to one of ordinary skill in the art to provide a stabilization device that engages with the a GI tissue, as taught by Laufer et al., to Koike et al. since it was known in the art that tissue piercing elements may injure or tear tissue from translating or puncturing, as well

[2] The Koike / Gannoe combination is the foundation of the rejections of all but claims 39 and 40. The Office's failure to provide any legitimate support for the proposed combination negates any possibility of there being a prima facie case of obviousness.

as withdrawing, retracting movement if the tissue is not stabilized and a stabilization device may prevent injury to the tissue.

Rather than preventing injury to the tissue – a function that is not mentioned in any of the references cited in the Office Action – the Laufer stabilization device is used to pull tissue between the end effector jaws prior to closing the jaws to deploy the fixation device. (Laufer, paragraphs 0095-96; Figures 9D-E). This function is not relevant to the methods taught in either of the Koike or Gannoe patents.

In order to support a rejection of claims for obviousness under section 103, the Office is obliged to provide an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of the cited references. M.P.E.P. § 706.02(j) (citing Ex parte Clapp, 227 USPQ 972, 973 (BPAI 1985)). In the present case, as demonstrated above, the reasons set forth in the Office Action are not supported by the art of record, nor by any evidence of general knowledge in the art. Accordingly, on the present record, there is no legitimate reason why a person skilled in the art would have been motivated to combine the teachings of the Koike, Gannoe, and Laufer references.

For these reasons, the rejections of claims 1, 3-7, 9, and 36-38 are improper and should be reversed.

(2) Claims 26, 32, and 35 and claims dependent therefrom

Independent claims 26, 32, and 35 are presented below:

26. A method for creating a gastrointestinal tissue fold, comprising:

providing a delivery catheter having a translatable needle and an anchor disposed within the needle and a suture coupled to the anchor;

engaging and pulling a tissue wall of the gastrointestinal lumen to create a tissue fold;

extending the needle through the tissue fold;

ejecting the anchor from the needle;

withdrawing the needle from the tissue fold whereby the suture is extended through the tissue fold;

translating a fastener over the suture; and

maintaining the tissue fold via the anchor and the suture.

32. (Previously Presented) A method comprising:

moving a catheter into a patient;

holding a tissue fold within the patient;

extending a piercing element from the catheter through the tissue fold;

moving a first anchor out from the piercing element, on a first side of the tissue fold;

withdrawing the piercing element from the tissue fold;

moving a second anchor out from the piercing element, on a second side of the tissue fold;

holding the tissue fold via a connection element connecting the first and second anchors; and

advancing a fastener over said connection element to apply a tension force on said connection element.

35. (Previously Presented) A method of creating a tissue fold comprising:

moving a catheter to a surgical site of a patient;

engaging and pulling a tissue wall to form a tissue fold;

pushing a piercing element extending out of the catheter through the tissue fold;

ejecting a first anchor from the piercing element;

withdrawing the piercing element from the tissue fold;

ejecting a second anchor from the piercing element, said second anchor being connected to said first anchor by a suture; and

advancing a fastener over said suture to apply a tension force on said suture;

with the anchors and the suture maintaining the tissue fold.

The Office rejected claims 26, 32, and 35 under 35 U.S.C. § 103(a), alleging the claims to be unpatentable over the same combination of Koike in view of Gannoe, Laufer, and Saadat discussed in the previous section. There are several reasons why

these rejections cannot be maintained, including all of the reasons set forth in the previous section, which are incorporated by reference here.

In addition, the Office Action states, at page 5:

> It would have been obvious to one of ordinary skill in the art to provide the step of creating a tissue fold, as taught by Gannoe et al., to Koike et al., since it was known in the art that obesity may be treated by forming folds in the gastrointestinal lumen which aids obese patients in managing the amount of food desired and eaten.

To the extent that this conclusion is understood, it is not supported by either of the cited references or by the general knowledge in the art. Even accepting the allegation concerning the knowledge in the art, the Koike patent is not concerned with "forming folds in the gastrointestinal lumen" or with "managing the amount of food desired and eaten." There is nothing in either of these patents, or in the art in general, that supports applying this teaching to the method taught by Koike.

As stated above, in order to support a rejection of claims for obviousness under section 103, the Office is obliged to provide an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of the cited references. M.P.E.P. § 706.02(j) (citing Ex parte Clapp, 227 USPQ at 973). In the present case, as shown above, the reasons set forth in the Office Action are not supported by the art of record, nor by any evidence of general knowledge in the art, nor by any sensible argument. Accordingly, on the present record, there is no legitimate reason why a person skilled in the art would have been motivated to combine the teachings of the Koike, Gannoe, and Laufer references.

For these reasons, the rejections of claims 26, 27, and 32-35 are improper and should be reversed.

B. The Office erred in rejecting claims 2 and 16 under 35 U.S.C. § 103(a) as being unpatentable over the Koike patent in view of the Gannoe patent, the Laufer publication, the Saadat patent, and the Matsui patent.

Claims 2 and 16 depend from claims 1 and 6, respectively. The reasons why claims 1 and 6 are patentable over the Koike, Gannoe, Laufer, and Saadat patents are set forth in section A above. The Matsui patent does not correct the defects of the foregoing

combination of references. Accordingly, the rejections of claims 2 and 16 are not supportable for the same reasons set forth above. These rejections should also be reversed.

C. The Office erred in rejecting claims 39 and 40 under 35 U.S.C. § 103(a) as being unpatentable over the McGuckin patent in view of the Adams patent.

Independent claims 39 and 40 are presented below:

39. A method comprising:

moving a catheter into a patient;

holding a tissue fold within the patient;

extending a piercing element from the catheter through the tissue fold;

moving a first anchor out from the piercing element, on a first side of the tissue fold;

withdrawing the piercing element from the tissue fold;

moving a second anchor out from the piercing element, on a second side of the tissue fold; and

holding the tissue fold via a connection element connecting the first and second anchors.

40. A method comprising:

moving a catheter having a tissue grasper and a piercing element into a patient;

holding a tissue fold within the patient with the tissue grasper;

extending the piercing element from the catheter through the tissue fold;

moving a first anchor out from the piercing element, on a first side of the tissue fold;

withdrawing the piercing element from the tissue fold;

moving a second anchor out from the piercing element, on a second side of the tissue fold; and

holding the tissue fold via a connection element connecting the first and second anchors.

The Office rejected claims 39 and 40 under 35 U.S.C. § 103(a), alleging the claims to be unpatentable over a combination of the McGuckin and Adams patents. As demonstrated below, there is no legitimate reason why a person of ordinary skill in the art would have been motivated to combine these references and modify their teachings in the manner suggested in the Office Action. As a result, the claims at issue are demonstrably patentable.

Turning to the Office Action, the primary reference – McGuckin – describes a system and method for resectioning gastroesophageal tissue. The system includes a stapling apparatus 10 and a separate grasping device 30 that extends through a lumen of an endoscope 20. (McGuckin, col. 3, ll. 23-40; Figures 1 and 2a-c). The stapling apparatus 10 includes a C-shaped stapling assembly 16 disposed on the distal end of a flexible body portion 14. (McGuckin, col. 3, ll. 41-48). The Office Action states:

> McGuckin discloses moving a catheter 10 into a patient, holding a tissue fold T within the patient with a tissue grasper 30, and extending a piercing element 16 from the catheter through the tissue fold (Figures 21-22).
>
> Although McGuckin acknowledges that the piercing element may be a stapling apparatus or a tissue approximating device, McGuckin does not expressly disclose using first and second anchors on first and second sides, respectively, of the tissue fold to approximate the tissue.

(Office Action, pg. 8). The Office Action relies upon the Adams patent to supply the subject matter missing from McGuckin.

Adams describes a method and device for performing endoluminal fundoplication. A distal end of a T-fastener 42 is ejected from a hypotube 40 and deployed on the stomach side of an intussuseption of the esophagus into the stomach, after which the hypotube 40 is withdrawn and the proximal end of the T-fastener 42 is deployed against the inner wall of the esophagus. (Adams, col. 6, ll. 3-24; Figures 5-7).

As stated above, an invention composed of several elements "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR, 127 S.Ct. at 1741. Absent a legitimate reason why a person skilled in the art would have been motivated to make the proposed combination, no prima facie

case of obviousness can be established. Such is the case with the McGuckin and Adams patents.

The entire justification set forth in the Office Action for combining the teachings of the McGuckin and Adams patents is the following:

> It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of McGuckin by adding first and second anchors on either side of the tissue fold, as taught by Adams et al., since it was well known in the art to use anchors which have an increased area over which the forces of securing the tissue will be distributed (col. 6, lines 25-36).

(Office Action, pg. 8). This conclusion is far too broad to support as such a general proposition. It is also based on a misreading of the cited portion of the Adams patent. The point made in the Adams patent is that T-bar fasteners with multiple bolsters (e.g., Adams Figures 9-11) are less likely to pull through tissue in comparison with traditional T-fasteners with a simple T-bar at each end (e.g., Adams Figure 8). This says nothing about whether it would have been obvious to modify the McGuckin stapling device and method to incorporate the Adams T-bar fasteners in some manner.

On the other hand, the proposed modification of the McGuckin device and method to incorporate T-bar fasteners (as taught by Adams) would require a substantial reconstruction and redesign of the McGuckin device (and method) as well as a change in the basic principle under which the McGuckin device is intended to operate. Staple deployment, as taught by McGuckin, requires driving an I-beam member axially through a stapling assembly where the axial motion of the I-beam is translated into perpendicular motion of a plurality of staple pushers that drive staples through tissue. (See McGuckin, col. 6, ll. 12-31, Fig. 15). The Adams T-bar fasteners, on the other hand, are deployed by expelling the fastener directly out of the distal end of a hollow delivery device. (See Adams, col. 6, ll. 3-23, Figs. 5-7). These are not mechanisms that are readily substituted for one another, insofar as they operate on very different principles in terms of deployment force transmission and resultant tissue securing properties. As a result, the teachings of the McGuckin and Adams patents are insufficient to support a prima facie case of obviousness. See, e.g., In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Accordingly, on the present record, there is no legitimate reason why a person skilled in the art would have been motivated to combine the teachings of the McGuckin and Adams patents in the manner proposed in the Office Action. For these reasons, the rejections of claims 39 and 40 are improper and should be reversed.

D. CONCLUSION

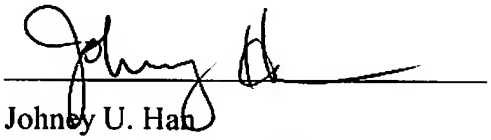
It is clear from the foregoing analyses that, rather than properly providing some legitimate teaching, suggestion, or motivation to combine the Koike, Gannoe, Laufer, Saadat, and Matsui patents and publications, or the McGuckin and Adams patents, the Office has relied upon the teachings of Appellants' claims to select discrete features from these references and combine them in a way that neither supportable by nor consistent with the references themselves. "To draw on hindsight knowledge of the patent invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction – an illogical and inappropriate process by which to determine patentability." Sensonics Inc. v. Aerosonic Corp., 81 F.3d 1566, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996), citing W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). "The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made." Id., citing Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

In the present case, the Office has provided no legitimate teachings, suggestions, or motivations to perform the multiple modifications necessary to arrive at the inventions recited in Appellants' claims. Rather, the Office has relied upon mischaracterizations of the teachings of the cited references, or has proposed advantages or objectives that are irrelevant to any of the methods taught by those references, to arrive at those claims. When these illegitimate contentions are properly stripped away, the only thing left is improper hindsight.

CONCLUSION

For at least the reasons set forth above, the Office has failed to present a prima facie case of obviousness against any of the claims on appeal. Consequently, reversal of the rejections of those claims is respectfully requested.

Respectfully submitted,



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VIII. CLAIMS APPENDIX

1. A method for delivering an anchor for use in a gastric reduction system for reducing the cross-sectional area of a gastrointestinal lumen, comprising:

providing a delivery catheter having a needle translatably disposed therein, a distal end, a stabilization device disposed at the distal end and one or more anchors disposed within the needle;

advancing the delivery catheter into the gastrointestinal lumen;

engaging the stabilization device to a tissue wall of the gastrointestinal lumen;

advancing the needle through the tissue wall;

ejecting an anchor from a distal tip of the needle, the anchor having a suture attached thereto;

withdrawing the needle from the tissue wall whereby the suture is extended through the tissue wall; and

translating a fastener over the suture whereby a tension force is created on the suture and said tissue fold is maintained.

2. The method of claim 1, further comprising: providing an imaging element in the vicinity of the distal end of the delivery catheter; and using the imaging element to provide visual guidance during engagement of the stabilization device to the tissue wall.

3. The method of claim 1, wherein ejecting an anchor from a distal tip of the needle comprises translating a push rod disposed in the needle.

4. The method of claim 1, wherein the stabilization device comprises a coil having a sharpened tip, and engaging the stabilization device to the tissue wall comprises rotating the coil to engage the coil into the tissue wall.

5. The method of claim 1, wherein advancing the needle through the tissue wall further comprises translating the needle distally through the delivery catheter.

6. A method comprising:

providing a delivery catheter including a piercing element within the catheter, one or more anchors within the catheter and a suture coupled to the anchors;

advancing the delivery catheter into the gastrointestinal tract of a patient;

advancing the piercing element through a first tissue wall, and then through a second tissue wall;

ejecting a first anchor from the piercing element on a first side of the first tissue wall, and ejecting a second anchor from the piercing element on a second side of the second tissue wall; and

advancing a fastener over the suture whereby a tension is applied to the suture, the fastener comprising a collar having a central channel through which the suture extends;

such that the first and second anchors and the suture hold the first tissue wall adjacent to the second tissue wall.

7. The method of claim 6, further comprising: providing a stabilization device on the delivery catheter; and engaging the stabilization device to the first tissue wall before advancing the catheter through the first tissue wall.

8. (Cancelled)

9. The method of claim 7, wherein the stabilization device comprises a tissue holding element.

10-15. (Cancelled).

16. The method of claim 6, further comprising: providing an imaging element in the vicinity of the distal end of the delivery catheter; and using the imaging element to provide visual guidance.

17-25. (Cancelled).

26. A method for creating a gastrointestinal tissue fold, comprising:

providing a delivery catheter having a translatable needle and an anchor disposed within the needle and a suture coupled to the anchor;

engaging and pulling a tissue wall of the gastrointestinal lumen to create a tissue fold;

extending the needle through the tissue fold;

ejecting the anchor from the needle;

withdrawing the needle from the tissue fold whereby the suture is extended through the tissue fold;

translating a fastener over the suture; and

maintaining the tissue fold via the anchor and the suture.

27. The method of claim 26, further comprising: providing a second anchor including a suture coupled thereto; and creating a second tissue fold on an opposing tissue wall.

28-31. (Cancelled).

32. A method comprising:

moving a catheter into a patient;

holding a tissue fold within the patient;

extending a piercing element from the catheter through the tissue fold;

moving a first anchor out from the piercing element, on a first side of the tissue fold;

withdrawing the piercing element from the tissue fold;

moving a second anchor out from the piercing element, on a second side of the tissue fold;

holding the tissue fold via a connection element connecting the first and second anchors; and

advancing a fastener over said connection element to apply a tension force on said connection element.

33. The method of claim 32 wherein forming the tissue fold results in reducing the cross sectional area of a lumen in the patient.

34. The method of claim 32 wherein forming the tissue fold reduces the volume of an organ in the patient.

35. A method of creating a tissue fold comprising:

moving a catheter to a surgical site of a patient;

engaging and pulling a tissue wall to form a tissue fold;

pushing a piercing element extending out of the catheter through the tissue fold;

ejecting a first anchor from the piercing element;

withdrawing the piercing element from the tissue fold;

ejecting a second anchor from the piercing element, said second anchor being connected to said first anchor by a suture; and

advancing a fastener over said suture to apply a tension force on said suture;

with the anchors and the suture maintaining the tissue fold.

36. The method of claim 6 wherein bringing the first and second tissue walls adjacent results in reducing the cross sectional area of an opening in the patient.

37. The method of claim 6 wherein bringing the first and second tissue walls adjacent results in reducing the volume of an organ of the patient.

38. A method comprising:

providing a system having a delivery catheter having a translatable needle and anchors disposed within the needle, and a suture coupled to the anchors;

engaging and pulling a tissue wall of the gastrointestinal tract of a patient to create a tissue fold;

extending the needle through the tissue fold;

placing an anchor on one side of the tissue fold;

releasing the tissue fold;

placing an anchor on the opposite side of the tissue fold, with the anchors connected to each other via the suture; and

advancing a fastener over said suture to apply a tension force on said suture;

with the anchors and suture maintaining the tissue fold after the tissue fold is released.

39. A method comprising:

moving a catheter into a patient;

holding a tissue fold within the patient;

extending a piercing element from the catheter through the tissue fold;

moving a first anchor out from the piercing element, on a first side of the tissue fold;

withdrawing the piercing element from the tissue fold;

moving a second anchor out from the piercing element, on a second side of the tissue fold; and

holding the tissue fold via a connection element connecting the first and second anchors.

40. A method comprising:

moving a catheter having a tissue grasper and a piercing element into a patient;

holding a tissue fold within the patient with the tissue grasper;

extending the piercing element from the catheter through the tissue fold;

moving a first anchor out from the piercing element, on a first side of the tissue fold;

withdrawing the piercing element from the tissue fold;

moving a second anchor out from the piercing element, on a second side of the tissue fold; and

holding the tissue fold via a connection element connecting the first and second anchors.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.